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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,440	06/23/2000	Wilfried Fischer	2727-110	9975

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/602,440

**Applicant(s)**

FISCHER ET AL.

**Examiner**

Humera N. Sheikh

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002 (paper no. 15).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### **Status of the Application**

Acknowledgement is made of the receipt of the Request for Reconsideration under CFR 1.114 (RCE), the Request for an Extension of Time (2 months) and the Preliminary Amendment, all filed 10/28/02.

Claims 1-10 are pending. New claims 9-10 have been added. Claims 1-10 are rejected.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann et al. (US Pat. No.5, 538,736, collectively, "Hoffmann").

Hoffmann teaches an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties, wherein the active substance-containing plaster can also contain further additives, such as plasticizers (see reference column 1, lines 20-44), (column 3, lines 17-40); (column 5, lines 1-35); (column 8, lines 11-16, 25-57). The active-substance containing plaster contains a back side, a skin side with a back layer, an active substance reservoir which can contain one or more active substances, a contact adhesive device on the skin side and optionally a detachable cover layer, wherein the part of the active substance reservoir part that remains on the skin, has better adhesion to the skin than the back layer (abstract). Hoffmann teaches that apart from the basic materials, the plaster can also contain further suitable additives, such as solubilizers, softeners, plasticizers, tackifiers, stabilizers, fillers and enhancers (col. 8, lines 11-16). The plaster can be used as a transdermal therapeutic system for the controlled administration of medical active substances or also cosmetically active substances to human or animal skin (col. 1, lines 32-43). Figure 1 demonstrates a two-part adhesive active substance-containing reservoir wherein the adhesion of the first active substance reservoir part to the skin must be greater than the adhesion between the peel-off layer and the back layer (col. 4, lines 50-67 through col. 5, lines 1-9). The back layer can be permeable or impermeable and suitable materials for the production

Art Unit: 1615

thereof are for example, polymeric substances, such as polyethylene and polypropylene. Permeable back layers are, for example, textile fabrics, such as non-woven fabrics, and the like (col. 8, lines 25-38). The detachable protective layer can be made detachable by applying a silicone layer. Other detachable protective layers are for example, polyvinylchloride, treated paper cellophane, etc. (col. 8, lines 45-53).

Hoffmann while teaching an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties, does not explicitly teach that the layer of adhesive is specifically rendered flowable by the addition of a plasticizer. However, Hoffmann does teach a plaster comprising two different adhesives, each with distinct adhesion properties and in addition teaches that suitable additives, such as plasticizers can also be contained in the plaster (col. 8, lines 11-16). Since the prior art teaches the use of plasticizers in the active substance-containing plaster, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include various suitable additives, particularly plasticizers, because they may serve to affect the bonding or flow properties of adhesion. The expected result would be an active substance-containing plaster for the release of medically active or cosmetically active substances to human or animal skin having distinct or different flowable adhesion properties as similarly desired by the applicant.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600